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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX-DGC
Lisa Hyde and Mark E. Hyde, a married couple, Plaintiffs, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00893-PHX-DGC **ORDER**

The case brought by Plaintiffs Lisa and Mark Hyde is set for a bellwether trial later this month. The parties have filed motions in limine ("MILs") in advance of trial. This order will rule on Plaintiffs' MILs Nos. 4 and 5, which seek to exclude evidence regarding the Bard IVC filter's instructions for use ("IFU") and certain guidelines published by the Society of Interventional Radiologists ("SIR"). Docs. 12100, 12101.

I. Background.

Plaintiff Lisa Hyde received a Bard IVC filter implant in 2011. In 2014, she learned that the filter had tilted, perforated the IVC wall, and fractured. The filter and

fractured limbs were removed three months later.[1]

Mrs. Hyde and her husband assert various claims. Doc. 364; Doc. 1, Case No. CV-16-00893. Applying Wisconsin law, the Court granted summary judgment on their failure to warn claims (Counts II and VII). Doc. 12007. Plaintiffs continue to assert claims for strict liability design defect (Count III), negligent design (Count IV), negligence per se (Count IX), loss of consortium (Count XV), and punitive damages. *Id.* at 19.

II. Discussion.

A. Parties' Arguments.

Under Wisconsin's product liability statute, Wis. Stat. § 895.047, a product is defective in design if its foreseeable risks of harm could have been reduced or avoided by the adoption of a reasonable alternative design, and the omission of the alternative design renders the product not reasonably safe. § 895.047(1)(a). Plaintiffs argue that, consistent with the statute, the focus of their case will be on the design of the Bard filter and alternative designs that would have made the filter safe. Doc. 12100 at 2. Plaintiffs argue that because the IFU says nothing about the filter's design, and because the failure to warn claims have been dismissed, the instructions and warnings set forth in the IFU are no longer relevant to any issue in the case and should be excluded under Rules 401 and 402 of the Federal Rules of Evidence. *Id.* at 2-3. Plaintiffs further argue that evidence regarding the IFU should be excluded under Rule 403 because it would only confuse the jury. *Id.* at 3.

Plaintiffs seek exclusion of the SIR guidelines for similar reasons. Doc. 12101. They argue that the purpose for which the SIR guidelines were previously admitted – to show knowledge of IVC filter complications in the medical community – is no longer relevant now that the failure to warn claims have been dismissed. *Id.* at 2. Plaintiffs contend that any defense based on the learned intermediary doctrine is moot without a

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[1] The parties dispute whether Mrs. Hyde's filter was a G2X or an Eclipse, but the filter type has no bearing on these MILs.

failure to warn claim, and that the defense otherwise does not apply because Mrs. Hyde, not the implanting physician, is the "ultimate consumer" under Wisconsin product liability law. *Id.*; Doc. 12100 at 3 (citing *Green v. Smith & Nephew AHP, Inc.*, 629 N.W.2d 727, 752 (Wis. 2001) (holding that a product is defective if it is in a condition "not contemplated by the ultimate consumer")).[2]

Defendants assert that the language of § 895.047(a)(1) reflects Wisconsin's adoption of § 2(b) of the Restatement (Third) of Torts (1998) ("§ 2(b)"). Docs. 12384 at 2, 12385 at 2. The IFU and SIR guidelines are relevant to the design defect claim, Defendants argue, because § 2(b) involves a risk-utility balancing test and consideration of a broad range of factors, including the instructions and warnings accompanying the product. *Id.* (citing § 2, cmts. d & f). Defendants further argue that Plaintiffs' reliance on *Green* and the "consumer contemplation" test is misplaced because the test has been abrogated by Wisconsin's adoption of § 895.047 and § 2(b). Doc. 12385 at 2 n.2.[3]

B. Wisconsin's Product Liability Law.

In 1967, Wisconsin adopted the rule of strict product liability set forth in the Restatement (Second) of Torts § 402A (1965) ("§ 402A"). *See Dippel v. Sciano*, 155 N.W.2d 55, 63-65 (1967). Eight years later, the state explicitly adopted a "consumer contemplation" test. *See Vincer v. Esther Williams All-Aluminum Swimming Pool Co.*, 230 N.W.2d 794, 797 (Wis. 1975) (adopting § 402A, cmts. g & i); *Green*, 629 N.W.2d at 738-39. Under this test, a product "is defective and unreasonably dangerous when it is in a condition not contemplated by the ultimate consumer and unreasonably dangerous to that consumer." *Beacon Bowl, Inc. v. Wis. Elec. Power Co.*, 501 N.W.2d 788, 809 (Wis. 1993) (citing *Vincer*).

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[2] It is not clear under Wisconsin law whether Mrs. Hyde or the implanting physician was the "ultimate consumer" of the Bard filter for purposes of the design defect claim. The Wisconsin Supreme Court has not decided whether to adopt the learned intermediary doctrine, and federal courts applying Wisconsin law are split on the issue. *See* Doc. 12007 at 14 n. 6 (citing cases).

[3] These arguments, and Wisconsin product liability law, are discussed by the parties more fully in their trial briefs and proposed pretrial order and jury instructions. Docs. 12358 at 2-15, 12400 at 8-13; Doc. 12388 at 19-22; Doc. 12438 at 34, 45-51.

The consumer contemplation test was challenged in *Green*. The defendant argued that a pure consumer contemplation test, without consideration of the risks and benefits of the product, would unnecessarily cause many useful products to be taken off the market. *Green*, 629 N.W.2d at 742. The defendant further argued that foreseeability of the risk of harm should be an element of product liability claims in order to avoid imposing absolute liability on manufacturers. *Id.* at 744. The defendant urged the court to adopt Restatement § 2(b), which includes an element of foreseeability:

> [A product] is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design[,] . . . and the omission of the alternative design renders the product not reasonably safe[.]

See id. at 751.

Green rejected these arguments. *Id.* at 737-52. The court declined the "invitation to abandon or qualify [Wisconsin's] exclusive reliance on the consumer-contemplation test." *Id.* at 743. The court also declined to adopt § 2(b) because its incorporation of "an element of foreseeability of risk of harm and a risk-benefit test . . . departs from the consumer-contemplation test set forth in [§ 402A], and blurs the distinction between strict products liability claims and negligence claims." *Id.* at 751 (noting that a risk-benefit test is included in § 2, comment a). The court was "troubled by the fact that § 2(b) sets the bar higher for recovery in strict products liability design defect cases than in comparable negligence cases" by adding the requirement that "there was a 'reasonable alternative design' available to the product's manufacturer." *Id.* The court concluded:

> Where a manufacturer places a defective and unreasonably dangerous product into the stream of commerce, the manufacturer, not the injured consumer, should bear the costs of the risks posed by the product. Because 2(b) unduly obstructs this equitable principle, we refuse to adopt 2(b) into Wisconsin law.

Id.

In early 2011, the Wisconsin legislature changed this law by enacting § 895.047. *See Gopalratnam v. Hewlett-Packard Co.*, No. 13-CV-618-PP, 2016 WL 8193573, at *1

(E.D. Wis. Mar. 11, 2016) (citing Wis. Senate Bill 1, 2011 Wis. Act 2 (Jan. 27, 2011)); *In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 218 F. Supp. 3d 700, 723 (N.D. Ill. 2016) (discussing § 895.047 and noting that it was "enacted as a part of a 'tort reform' initiative in 2011"), *aff'd* 884 F.3d 746 (7th Cir. 2018). The new statute adopted § 2 of the Restatement (Third). Doc. 12400 at 11. The statute reads:

> **(1) Liability of manufacturer.** In an action for damages caused by a manufactured product based on a claim of strict liability, a manufacturer is liable to a claimant if the claimant establishes all of the following by a preponderance of the evidence:
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> (a) That the product is defective because it . . . is defective in design . . . . A product is defective in design if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe.

§ 895.047(1)(a); *see Lexington Ins. Co. v. Whesco Grp., Inc.*, No. 11-CV-598-BBC, 2013 WL 4454959, at *8 (W.D. Wis. Aug. 16, 2013); WIS JI-CIVIL § 3260.1 (2014). Thus, a plaintiff claiming strict product liability under Wisconsin law must now show that the product's foreseeable risk of harm could have been reduced or avoided by a reasonable alternative design, and that the failure to adopt the alternative design rendered the product "not reasonably safe." § 895.047(1)(a).

C. Analysis.

Plaintiffs rely on *Green* in arguing that the IFU and the SIR guidelines have no relevance to the design defect claim because "a product is not reasonably safe under Wisconsin law if it is 'in a condition not contemplated by the ultimate consumer.'" Doc. 12101 at 2 (quoting *Green*, 245 Wis. 2d at 825-26); *see* Doc. 12100 at 3. But *Green* was effectively overruled by the adoption of § 895.047, and the consumer contemplation test is now only one factor in determining whether the Bard filter was unsafe. The statute adopts § 2 of the Restatement, and, under § 2, "consumer expectations do not constitute an independent standard for judging the defectiveness of product designs" because they do not take into account "whether an alternative design would provide greater overall

safety." *See* Restatement (Third) § 2, cmt. g; *see also* WIS JI-CIVIL § 3260.1 (noting that § 895.047(1)(a) introduced the "reasonable alternative design" test for design defect cases "apparently discarding the consumer contemplation test"). Thus, the Court cannot exclude the IFU and SIR guidelines on the basis urged by Plaintiff – that they are not relevant to consumer expectations.[4]

Plaintiffs further argue that the IFU and SIR guidelines are no longer needed to support a learned intermediary defense because the failure to warn claims have been dismissed. Docs. 12100 at 1-2, 12101 at 2. Those claims have been dismissed, but the IFU and SIR guidelines are also relevant to the design defect claim. As noted above, the jury must consider not only whether there was a reasonable alternative design, but also whether Bard's failure to adopt that design rendered the filter "not reasonably safe." Wis. Stat. § 895.047(1)(a). The SIR guidelines – created by the Society of Interventional Radiologists to inform the medical community regarding acceptable rates of risk in IVC filters – are relevant to the jury's determination of whether Bard's filter was reasonably safe. Bard's IFU, including what it tells physicians about risks of the Bard filters and how to mitigate them, is also relevant in determining whether the filter was reasonably safe. Nothing in § 895.047 precludes Defendants from arguing to the jury that the warnings provided with the Bard filter disclosed the risks of complications, that the medical community was aware of those risks and found them to be acceptable, and that the omission of an alternative design therefore did not render the filter "not reasonably safe."[5]

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[4] Plaintiffs note in their trial brief that comment g to § 2(b) provides that consumer expectations, while not dispositive, still play a role in determining defectiveness. Doc. 12400 at 10-11. A Wisconsin district court has expressed doubt whether this "is an accurate statement of the law in Wisconsin." *In re Zimmer*, 218 F. Supp. 3d at 723. The Court need not decide this issue for purposes of the MILs because consumer expectations are, at most, only one factor to be considered in the ultimate determination of whether the omission of a proposed alternative design renders a product not reasonably safe. *See id.*; § 895.047(1)(a).

[5] Defendants note that a comment to the Restatement provides that the instructions and warnings accompanying a product may be considered in determining whether a product is defective. Docs. 12384 at 2, 12385 at 2 (citing § 2, cmt. f). Based on this and other comments to the Restatement, Defendants propose jury instructions setting forth a

The IFU and SIR guidelines also are relevant to Plaintiffs' negligence and punitive damages claim. In deciding whether Defendants acted reasonably for purposes of the negligence claim, the jury may consider rates of risk accepted within the medical community (the SIR guidelines) and what Defendants told physicians about those risks in the IFU.

To recover punitive damages under Wisconsin law, Plaintiffs must show that Defendants "acted maliciously" or in an "intentional disregard of the rights" of Plaintiffs. Wis. Stat. 895.043(3); *see Strenke v. Hogner*, 694 N.W.2d 296, 304-05 (Wis. 2005). The jury may consider Defendants' "attitude and conduct" and "the degree of [Defendants'] awareness of the hazard and of its excessiveness." Doc. 12438 at 38-39; *see* WIS JI-CIVIL § 1707.2. Warnings provided in the IFU are relevant to Defendants' attitude and conduct toward patients who receive Bard filter implants, and whether Defendants acted with malice or an intentional disregard for patient safety. The SIR guidelines are relevant to Defendants' awareness of filter complication rates and the extent of harm posed by filter complications, and can also inform the jury of risk levels found acceptable by interventional radiologists – a relevant fact for deciding whether Defendants' acted with a disregard for patient safety.

Plaintiffs contend that the IFU should be excluded under Rule 403. Docs. 12100 at 3. But evidence regarding the IFU will not unfairly prejudice Plaintiffs or confuse the jury. Defendants will not be permitted to assert a learned intermediary defense or otherwise defend against the dismissed failure to warn claims, and the Court will properly instruct the jury on the claims at issue and the law that applies to them.

Plaintiffs contend that any probative value of the SIR guidelines is substantially outweighed by the dangers described in Rule 403 because no expert has testified that the SIR guidelines set forth "acceptable" complication rates. Doc. 12101 at 2-4. But the

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host of factors the jury may consider in deciding whether the Bard filter is defective. Doc. 12438 at 46-48. Plaintiff objects to the proposed instructions, arguing that the comments to the Restatement have not been incorporated into Wisconsin product liability law. *Id.*; Doc. 12400 at 11 (trial brief). The Court need not decide this issue in order to resolve the MILs.

Court will require an appropriate foundation before admitting the SIR guidelines, and Plaintiffs' challenge to their veracity will go to their weight, not their admissibility.

IT IS ORDERED that Plaintiffs' MILs Nos. 4 and 5 (Docs. 12100, 12101) are **denied**.

Dated this 4th day of September, 2018.

David G. Campbell
Senior United States District Judge